



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2020-N-0025]**

#### **Availability of FDA Statement Added to the Docket for Public Meeting Related to Cosmetic Products Containing Talc**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a statement added to the docket for the public meeting entitled “Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc” to address information provided in connection with the public meeting. FDA held the public meeting on February 4, 2020, to discuss and obtain scientific data and information on topics related to cosmetic products with talc as an ingredient, specifically, testing methodologies, terminology, and criteria that could be applied to characterize and measure asbestos and other potentially harmful elongate mineral particles (EMPs) that may be present as contaminants in such products. The meeting included presentations by members of an interagency working group (the Interagency Working Group on Asbestos in Consumer Products or IWGACP).

**FOR FURTHER INFORMATION CONTACT:** Deborah Smegal, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Campus Dr., College Park, MD 20740, 240-402-1130.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

We opened a public docket and held a public meeting on February 4, 2020, to discuss and obtain scientific data and information on topics related to cosmetic products with talc as an ingredient, specifically, testing methodologies, terminology, and criteria that could be applied to characterize and measure asbestos and other potentially harmful EMPs that may be present as contaminants in such products. The meeting included presentations by members of an interagency working group (IWGACP).

As part of the meeting materials, FDA made available an Executive Summary titled “Preliminary Recommendations on Testing Methods for Asbestos in Talc and Consumer Products Containing Talc” by the IWGACP. Neither the Executive Summary nor any of the presentations at the public meeting by members of the IWGACP represent proposed or preliminary recommendations or policies of FDA or any other Federal Agency.

Recently, we have been made aware of concerns that some external parties may consider the Executive Summary to be FDA recommendations. As a result, we are announcing the availability of a statement in the public docket to address information provided in connection with the public meeting. We have also added corresponding content on FDA’s web page for cosmetics and talc (<https://www.fda.gov/cosmetics/cosmetic-ingredients/talc>).

These updates are intended to clarify that the Executive Summary and related presentations at the public meeting were meant solely to solicit scientific feedback on the issues raised and should not be used for any other purpose. FDA and members of the IWGACP continue to evaluate the scientific literature and public feedback to the docket. FDA does not have any recommendations at this time. Should FDA decide to develop recommendations with

respect to standards or testing methods for asbestos in talc, as a result of the information it received as part of the public meeting and comments to the public docket or otherwise, it would issue draft guidance for public comment. Likewise, FDA would propose any related regulations through a public notice and comment process.

## II. Electronic Access

Persons with access to the internet may obtain an electronic version of the document at either <https://www.fda.gov/cosmetics/cosmetic-ingredients/talc> or <https://www.regulations.gov>.

Dated: August 14, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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